MEETING SUMMARY
EXECUTIVE COMMITTEE CONFERENCE CALL
Convened in Ariel Rios North Building Room 6013
1200 Pennsylvania Avenue, Washington, DC
June 16, 2000 1:00 pm EDT

1. Attendees

EC Members present on the telephone:

Dr. Morton Lippmann, Chair
Dr. Henry Anderson
Dr. Linda Greer
Dr. Hilary Inyang
Dr. Janet Johnson
Dr. W. Randall Seeker
Dr. William Smith
Dr. Mark Utell
Dr. Terry Young

Dr. Ronald Kendall, Liaison from FIFRA Scientific Advisory Panel (SAP)
Mr. Thomas Carrato, Liaison from Children's Health Protection Advisory Committee (CHPAC)

Designated Federal Officer, present in AR 6013: Dr. Donald Barnes

Others present in AR 6013 and identified on the phone are noted on the attendance sheets (Attachment A)

2. Agenda

The meeting followed the agenda (Attachment B)

3. Consideration of the Joint SAB/SAP Committee's *"Report on Data from the Testing of Human Subjects"* (Attachment C)

SAB Co-Chair, Dr. Utell introduced the report noting the complexity and difficulty of the scientific and ethical issues involved in the topic. The Subcommittee was composed of SAB and SAP members, supplemented by various consultants from speciality areas, such as pediatrics and bioethics. The mix of backgrounds on the committee, both disciplinary and organizational, made for a challenging process. In the end, the group was able to generate a report that has been agreed to by all of the participants except two individuals, one of whom has filed a separate

minority report (Attachment D). Dr. Utell then proceeded to summarize the content of the report.

SAP Co-Chair, Dr. Kendall, noted the wide range of opinions represented on the Committee. He, too, commented on the difficulties encountered along the way. In particular, he noted that he had been a co-signer to a statement generated after the first meeting that cited procedural problems that led to the holding of a second meeting. He took exception to the minority report by stating that since he had become Co-Chair just prior to that meeting, there had been open discussion and wide distribution of all materials and opinions generated during the course of the Committee's deliberations. In particular, he cited the commendable work of the Designated Federal Officers, Larry Dorsey and Sam Rondberg, for their tireless, thorough, and professional service to the Committee. In sum, he felt that the report is a fair and accurate representation of the range of views of the Committee members.

Dr. Greer commented that there is a considerable difference between these oral reports and the process described in the minority report.

Mr. Rondberg updated the Executive Committee on his exchanges with Drs. Needleman and Reigart regarding the minority report. The Committee roster will include both men's names, since they participated in both public meetings and the subsequent drafting process. Their names will be asterisked with an indication that they dissociate themselves from the Committee report and filed a minority report that will be included in an appendix to the Committee's report.

Dr. Kendall observed that the current minority report repeats many of the concerns that were cited in the first statement generated after the first meeting which he and several other Committee members along with Drs. Needleman and Reigart. In his view, the current minority report does not reflect the considerable and significant process changes that have been instituted since he became Co-Chair. He also felt that the majority of the Committee agreed with the notion that there should not be a total ban on the testing of pesticides in humans; the question was how rigorous the restrictions should be and under what conditions the testing could/should take place.

Both this report and the next one that was considered by the EC (Children and Cancer) address contentious issues. The "tone" and form of presentation is somewhat different. In response to a question on the matter, Dr. Utell noted that this report on Children and Cancer deals with a specific Agency document according to a set of targeted Charge questions. In contrast, the report from the DTHSS deals with an issue for which the Agency does not have a specific document and whose Charge questions are of a more general nature. These characteristics elicited a range of views which come from them being expressed in the minority report.

DFO Sam Rondberg volunteered that there had been more agreement in the DTHSS than in the Subcommittee dealing with cancer. Both he and the other DFO, Larry Dorsey, noted that the current draft report reflects numerous changes and ideas suggested by Drs. Needleman and Reigart and that there was concern on the part of some of the other members of the Subcommittee that the language

was in danger of being changed too much in order to accommodate their dissenting views. Mr. Rondberg briefly reviewed and responded to the major allegations contained in the majority report.

Lead Discussant, Dr. Lippmann, had forwarded a number of editorial corrections/suggestions. He had no substantive concerns about the document.

Associate Discussant, Dr. Johnson, praised the Joint Committee's work, but raised a number of points:

a. She urged that the charge be summarized in the transmittal letter and in the Executive Summary.
b. She urged that the question of the matter of a non-exploitive remuneration be left in the hands of the Institutional Review Board (IRB).
c. She urged clarity about what data should -- and should not -- be accepted.
d. She urged elimination of any implication that a distinction be made between children, young children, adolescents, etc.
e. She urged that reference to what has been learned from the Chernobyl incident be eliminated or replaced by something that has produced more definitive information than Chernobyl has done to date; e.g., underground miners and radon.
f. She urged that the report provide some more background information on the Common Rule, the Helsinki Agreement, etc.

Dr. Utell indicated that these helpful comments could be accommodated.

Dr. Young addressed some points about the report that gave her significant concerns related to clarity, if not substance:

a. The impact of these recommendations on data gathered from studies conducted overseas. In response, Mr. Rondberg indicated that the Joint Committee treated the problem of foreign research activities; cf., Section 3.5.3. Dr. Utell indicated that they felt that the same principles and adherence to rigor should apply. More generally, the Joint Committee dealt primarily with the concepts, not a list of specific cases; it will be up to the Agency to react to and apply that advice in any given context.
b. The intent of item c) in the cover letter; e.g., "promise of reasonable benefits to the individual or society at large"
c. The intent of item d) in the cover letter; i.e., what is a developing human and why the limitation on neurotoxic chemicals?

Dr. Greer felt that she could not support the report and asked how her concerns might be expressed to the Administrator. She was assured that her concerns could be reflected in the cover letter that transmitted the report to Ms. Browner.

Dr. Smith also expressed concern about limited amount of information provided in the report on

fundamentally important issues, such as the structure and function of the Institutional Review Boards (IRBs). Dr. Utell indicated that such information is valuable and that a brief description/discussion will be included in an appendix.

Dr. Lippmann then turned to the members of the public who had expressed a desire to present comment to the EC. In each case, written comments had already been distributed to the EC:

a. Mr. Ed Gray (JSC, Inc.), representing Cheminova, provided oral comments (Attachment E) that amplified on his written comments (Attachment F) that had been circulated to the EC by email. In part, he urged the EC to carefully consider the point-by-point analysis of the Joint Committee's argument contained therein.

b. Mr. William Kelly of the Center for Regulatory Effectiveness provided oral comments that amplified on his written comments (Attachment G) that had been circulated to the EC by email. In part, he urged that the Agency not re-invent the Institutional Review Boards and/or the Common Rule and Helsinki Agreement.

c. Dr. James Wilson of Resources for the Future, provided oral comments that amplified on his written comments (Attachment H) that had been circulated to the EC by email. In part, he questioned the recommendation (item 5 in the cover letter) for a workshop in light of an earlier recommendation that human studies not be done for the sake of establishing NOAELs.

d. Dr. Daniel Swartz of the Children's Environmental Health Network provided oral comments that pursued some of the points raised in the minority report. The DFOs (Mr. Dorsey and Mr. Rondberg) took exception to the allegations concerning misconduct in the process. Dr. Kendall again offered his view that the process since the second meeting was as open, consistent, and fully informed as reasonably possible.

[e. For the record, Dr. Angelina Duggan of the American Crop Protection Association had provided written comments (Attachment I), which had been distributed to the EC, but chose not to request time for oral comments.]

ACTION 1: The Executive Committee approved the Joint SAB/SAP Committee's *"Report on Data from the Testing of Human Subjects"* subject to: a) edits referenced in the meeting, and b) final review by the following members: Drs. Johnson, Lippmann, Smith, and Young. In addition, Drs. Anderson and Greer will provide input/review to the transmittal letter.

4. Consideration of the EC Subcommittee's *"Applicability of the Agency's Cancer Risk Assessment Guidelines to Children"* (Attachment J)

Dr. Utell introduced the report by speaking of the range of opinions represented on the Subcommittee and the need to characterize that range appropriately and summarizing the major points of the report.

The Associate Discussant, Dr. Greer, expressed her preference for the method of characterizing the range of opinion used in this report. However, she cites numerous places where the technique of referring to "most of the Subcommittee . . . " or "some of the Subcommittee . . . " was confusing or incomplete. She will send Dr. Utell a marked up version of the report that highlights such places. In such cases, she recommended a clear statement to the effect that "The Subcommittee could not reach agreements on . . . " Dr. Utell indicated that these changes would help to clarify points in the report and, therefore, would be accommodated.

Dr. Greer also questioned the statement that the Subcommittee felt that the guidelines should be released even in the face of such unresolved issues. It was her understanding that this was not a unanimous view of the members of the Subcommittee. Dr. Utell responded that the Subcommittee's report, in common with earlier SAB reports, was simply expressing the view that the guidelines had been under development for the better part of a decade and that it was important to begin to use the guidelines in order to gain experience with them before the remaining issues could be resolved. The continued enthusiasm for release of the guidelines was based on this notion, rather than on any presumption that the current draft is -- or would even be -- completely without problems. He said that this was an important question and he would re-poll the Subcommittee on the question of the release of the guidelines in order to verify the group's earlier discussions.

Dr. Anderson, also a member of the Subcommittee underscored Dr. Utell's summary and observed that discussion of the guidelines was getting bogged down in discussion of a seemingly endless list of "what ifs." In his view, the discussion of theoretical questions now needed to be augmented with a dose of practical use.

The Lead Discussant, Dr. Seeker, agreed that it was important to clarify: a) the language to accurately reflect the range and balance of views on the Subcommittee, and b) the Subcommittee's views on the release of the guidelines. He felt that the review of the Agency's answers to the questions posed by the Children's Health Protection Advisory Committee (CHPAC) was awkward, at best. However, he encouraged the Subcommittee to capture some of the points made in the portion of the report in the Conclusions, Executive Summary, and transmittal letter.

Dr. Lippmann then turned to the members of the public who had expressed a desire to present comment to the EC.

a. Dr. Angelina Duggan of the American Crop Protection Association introduced Dr. Elliot Gordon of Makteshim who amplified on written comments (Attachment K) that had been circulated to the EC by email. In part, he questioned: a) the blanket assumption that children would always be more susceptible than adults, and b) the default assumption of linear-at-low-dose.

b. Dr. Daniel Swartz of the Children's Environmental Health Network had not supplied any written comments. In part, his oral comments alleged that, as in the case of the DTHSS report, he "had heard from Subcommittee members" that distribution of information to

and between the Subcommittee members was a problem. Dr. Utell and the DFO (Sam Rondberg) said that they had tried to be fair and diligent on this matter and that they had not received any indication from the members that their efforts had been found to be wanting in any way.

The EC continued the discussion of review of the Agency's response to the CHPAC questions. Dr. Barnes reported that when the CHPAC expressed interest in the issues surrounding the guidelines and he had worked with the CHPAC staff to pursue the EC's recommendation (stemming from the November 1997 Strategic Planning Retreat) to explore interactions with other FACA committees. In this instance the CHPAC had specific technical questions. Dr. Barnes devised this experiment of having the Board review the Agency response to the questions. Dr. Utell agreed somewhat cautiously to participate in this novel approach. Mr. Carrato, liaison participant from CHPAC, emphasized that his Committee was looking for an Agency answer to the questions. In fact, the CHPAC questions were appropriate, but difficult, and the Agency did not have adequate time to prepare thorough and effective answers. As a result, the SAB found the experiment to be less than a success. Mr. Carrato recommends that the Board capture this experience in some means and make recommendations for future improvements in the process.

INSTRUCTION 1: The Chair instructed Dr. Barnes to draft a EC Commentary regarding the experiment of addressing CHPAC questions to the Agency in the context of an SAB review. The Commentary should include lessons learned and suggestions for future improvements in the inter-FACA committee process.

ACTION 2: The Executive Committee approved the EC Subcommittee's*"Applicability of the Agency's Cancer Risk Assessment Guidelines to Children"* subject to: a) edits referenced in the meeting, and b) final approval by the vettors, Drs. Seeker and Greer.

With no other business to come before the EC, the meeting adjourned.

Respectfully Submitted,

/s/

Donald G. Barnes, Ph.D.
Designated Federal Officer

Certified as True,

/s/

Morton Lippmann, Ph.D.
Interim Chair, Executive Committee

ATTACHMENTS
EXECUTIVE COMMITTEE CONFERENCE CALL
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Attachment A -- Attendance sheets
Attachment B -- Agenda
Attachment C -- Joint SAB/SAP Committee's *"Report on Data from the Testing of Human Subjects"*
Attachment D -- Minority report from Drs. Needleman and Reigart
Attachment E -- Mr. Ed Gray's oral statement on the Joint SAB/SAP Committee's report
Attachment F -- Mr. Ed Gray's written statement on the Joint SAB/SAP Committee's report
Attachment G -- Mr. William Kelly's written statement on the Joint SAB/SAP Committee's report
Attachment H -- Dr. James Wilson's written statement on the Joint SAB/SAP Committee's report
Attachment I -- Dr. Angelina Duggan's written statement on the Joint SAB/SAP Committee's report
Attachment J -- EC Subcommittee's *"Applicability of the Agency's Cancer Risk Assessment Guidelines to Children"*
Attachment K -- Dr. Angelina Duggan's written statement on EC Subcommittee's report

ACTION ITEMS AND INSTRUCTIONS
EXECUTIVE COMMITTEE CONFERENCE CALL
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